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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,481	10/24/2003	Elazar Rabbani	ENZ-60(CIP)	2531

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ENZO BIOCHEM, INC.
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NEW YORK, NY 10022

EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/693,481

Applicant(s)

RABBANI ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-626 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 251-285 and 625 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/29/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's response filed 8/07/06 to the Office action has been entered. Claims 1-626 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group IX, claims 252-287 and 625 in the reply filed on 8//7/06 is acknowledged. The traversal is on the ground(s) that the restriction requirement is requested to be reconsidered based upon the reformulated restriction by Applicants as each group shares a single inventive concept. This is not found persuasive because as indicated in the Office action mailed 4/06/06, each group has its own components or its own method steps. Therefore, they are distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claims 286 and 287 are objected to because of the following informalities: the words "comprise" and "are" in claims 286 and 287 might be grammatical errors. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 251-287 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- a. Claims 251-287 are vague and indefinite because of the phrase “adding a non-inherent UDT” in the claims. It is unclear whether or not the non-inherent UDT is attached to the extended primers or the extended nucleic acid constructs. Clarification is required.
- b. Claims 269-280 are vague and indefinite because of the phrase “a production center”. It is unclear what is the definition of the phrase. Clarification is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claim 625 is rejected under 35 U.S.C. 102(e) as being anticipated by Laird et al. (6,94,142, issued Sep. 21, 2004).

Laird et al. disclose that a primer-based amplification involves repeated primer extensions, wherein at least one of the primers is a modified primer (See column 8, lines 55-57). The modified primer is at 3' terminus in which the 3' terminal nucleotides are a modified nucleotide, 2'-O-methyl-ribonucleotides (See column 6, lines 50-55). Based upon the teachings set forth above, the teachings of Laird et al. anticipate the limitation of the claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 251-263, 267, 269-285 and 287 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (6,197,554, issued Mar. 6, 2001) in view of Laird et al. (6,94,142, issued Sep. 21, 2004).

Lin et al. disclose a method for generating a complete full-length cDNA library from single cell (See column 2, lines 42-44). The method applies a homopolymer dT-promoter primer (See column 2, lines 52-55). The homopolymer dT-promoter primer is complementary to homopolymer dA of mRNA (See column 2, lines 52-57). A plurality of cDNAs is produced (See column 2, lines 58-60). The cDNA is tailed by terminal transferase reaction (See column 2, lines 60-64). The full length cDNA library can be made from extracted RNAs by the same steps from (b) to step (f) with the difference of total RNAs/mRNAs (See column 5, lines 12-15). Taq

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polymerase is used in the method (See column 7, line 5). The promoter sequence comprises T3, T7, or SP6 (See column 3, lines 28-31). The dNTPs and NTPs are used in the method (See column 6, lines 43-47). The labeling of the cDNA can be accomplished by incorporation of labeled nucleotides or analogs (See column 5, lines 19-21). The homopolymeric segment is comprised of T (See column 2, lines 54-55) or oligo-C or oligo-G or oligo-A (See column 3, lines 31-39).

Lin et al. do not disclose that the primer is modified at 3' terminal nucleotides with substitution of the 2' position of the ribose ring, providing the reagent comprising Mn^{++} , the labels recited in claims 278-280 and limitations recited in claims 282-283, 286 and 287.

Laird et al. disclose that a primer based amplification involves repeated primer extensions, wherein at least one of the primers is a modified primer (See column 8, lines 55-57). The modified primer is at 3' terminus in which the 3' terminal nucleotides are a modified nucleotide, 2'-O-methyl-ribonucleotides (See column 6, lines 50-55). DNA polymerase requires Mn^{++} , which is used to increase the efficiency of extension reactions using an RNA template (See column 9, lines 47-53). The mutant Tth DNA polymerases incorporate dNTPs and ddNTPs labeled with fluorescent (See column 13, lines 12-15). The modified primer is synthesized on a solid support (See column 8, lines 28-35). Laird et al. also disclose that at least one of said nucleotide analogues comprises a portion of said homopolymeric sequence or is different from the base comprising said homopolymeric segment (See column 12, lines 1-49) as recited in claims 286 and 287.

One of ordinary skill in the art would have been motivated apply a primer which is modified at 3' terminal comprising nucleotide analogue with substitution on the 2' position of

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ribose ring as taught by Laird et al. in the method of Lin et al. for synthesizing one or more copies of a library of nucleic acid targets because as disclosed by Laird et al., the use of oligonucleotide primers containing particular modification at or near the 3' terminus in a primer-based amplification is to reduce non-specific amplification (See column 3, lines 18-24). It would have been prima facie obvious to apply the primer which is modified at 3' terminal comprising nucleotide analogue with substitution on the 2' position of ribose ring for synthesizing one or more copies of a library of nucleic acid targets.

9. Claim 264-266, 268 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (6,197,554, issued Mar. 6, 2001) in view of Laird et al. (6,94,142, issued Sep. 21, 2004) as applied to claims 251-263, 267, 269-285 and 287 above, and further in view of Austermann et al. (Biochemical Pharmacology, 1992, Vol. 43(12), pg. 2581-2589).

The teachings of Lin et al. and Laird et al. are set forth in section 8 above. Lin et al. and Laird et al. do not disclose the step of adding a terminator nucleotide as recited in claims 264-266 and 268.

Austermann et al. disclose 3'-blocked oligonucleotide primers, which inhibit DNA synthesis catalyzed by HIV-1 reverse transcriptase (See pg. 2581, the Abstract). The oligonucleotide primers were elongated in a terminal transferase-catalysed reaction with ddATP (See pg. 2581, the Abstract and pg. 2584, column 1, third paragraph). The terminator is ddATP, or arabino-ATP (See pg. 2586, Table 3).

One of ordinary skill in the art would have been motivated to apply the 3'-blocked oligonucleotide primer as taught by Austermann et al. because the 3'-blocked oligonucleotide primer act as strong inhibitor of DNA synthesis catalyzed by HIV-1 reverse transcriptase (See

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pg. 2581, the Abstract). It would have been prima facie obvious to have a step of adding a terminator nucleotide by providing terminal dioxynucleotidyl transferase and a mixture of terminator and non-terminator for synthesizing one or more copies of a library of nucleic acid targets.

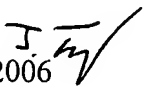
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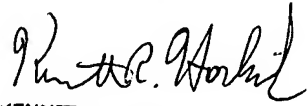
10. No claims are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung 
October 26, 2006


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

10/30/06